Meaningful Use Workgroup
Subgroup #4 – Population Health
Transcript
May 22, 2012

Roll Call

MacKenzie Robertson – Office of the National Coordinator

Good morning everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Policy Committee's Meaningful Use Workgroup, subgroup #4, Improving Population and Public Health. This is a public call and there will be time for public comment at the end. The call is also being transcribed, so please make sure you identify yourself before speaking. I'll go through roll and then at the end, ask any staff members to also identify themselves. Art Davidson?

Arthur Davidson – Denver Public Health Department – Director

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Art. Charlene Underwood? Amy Zimmerman? Marty Fattig?

Marty Fattig – Nemaha County Hospital (NCHNET)

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Marty. Yael Harris? George Hripcsak?

George Hripcsak – Columbia University

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks George. Are there any Meaningful Use Workgroup members on the line?

Deven McGraw – Center for Democracy & Technology – Director

Deven McGraw.

MacKenzie Robertson – Office of the National Coordinator

Thanks Deven. And are there any staff members?

Michelle Nelson- Office of the National Coordinator

Michelle Nelson, ONC.

MacKenzie Robertson – Office of the National Coordinator

Thanks Michelle.

James Daniel – Public Health Coordinator – Office of the National Coordinator

James Daniel, ONC, too.

MacKenzie Robertson – Office of the National Coordinator

Okay. I'll now turn it over to you Art.

Arthur Davidson – Denver Public Health Department – Director

Great, thank you. Good morning and thank you again MacKenzie. Once again I'd like to extend a warm thank you to Michelle Nelson and Jim Daniel for their work in organizing these sessions. We have an

excellent panel for testimony today. This is the second in a series of three planned listening sessions for the Population and Public Health Subgroup of the Meaningful Use Workgroup. The testimony we hear today will be evaluated by the Workgroup for recommendation back to the HIT Policy Committee. The process is such that our testimony today should inform the Advisory Role of the HIT Policy Committee in support of the mission of ONC and CMS as defined in the HITECH Act. We hope to have feasible, strong and well developed ideas emerge from these listening sessions. Our panel today certainly has a wealth of experience and knowledge about the exchange of information within their respective public health domains.

The third, and currently last planned listening session for this sub-committee is scheduled for next week, on 5/29, at the same time. Information about this and other meetings is available at the HealthIT.HHS.gov website and a simple web search for Meaningful Use Workgroup; subcommittee should get you to a page that allows you to see all the materials that have been posted there from the previous session and any subsequent sessions. This is an open meeting and the subcommittee seeks community input. If there are questions or comments, the telephone line will be open at the end of the meeting. If you have any comments for the committee, workgroup or subcommittee after this meeting, you can send them to ONC and they will be directed appropriately.

For today's session, each of the panelists was given a series of questions to help get the presentation organized and to support the subgroups mission. This is subgroup 4 of all the subgroups for the Meaningful Use Workgroup. These questions were: "What are you working on that can help inform Stage 3?" "What barriers have you faced?" "What infrastructure, policies, tools, training and/or communication is needed to make this successful?" And, "what strategies would you recommend to get there?" Panelists have each been asked to limit their comments to ten minutes, to assure time for questions and/or comments from the subgroup members and/or the public. So, I'll go ahead and read some biographies in the order in which people will be presenting. The panelists include: Rebecca Coyle, who is the Executive Director of the American Immunization Registry Association. Ms. Coyle is joined by Emily Emerson, who has been the Immunization Information System Manager in Minnesota since 2004. She is also the immediate past president of the American Immunization Registry Association and co-chair of the Standards and Interoperability Steering Committee.

Then we'll have presentation from Warren Williams. Mr. Williams works at the Centers for Disease Control and Prevention in the Immunization Information Systems Support Branch. He received a Masters' in Public Health from Emory University in 1991 and started working at the CDC in Atlanta at that time. Then, after Mr. Williams, we have Dr. Tom Shimabukuro, who is the Senior Medical Officer in the Immunization Safety Office in the Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases at the CDC. Following Dr. Shimabukuro, we have Dr. Birnbaum. Dr. David Birnbaum has 40 years of experience as a Hospital Epidemiologist and Infection Control Professional working in hospitals, academic positions as a consultant and as a software developer. He now manages the Washington State Health Departments Healthcare Associated Infections Program.

And lastly, we have Delton Atkinson, who is the Deputy Director of the Division of Vital Statistics within the CDC's National Center for Health Statistics, overseeing the reengineering of this Division's IT systems to improve the timeliness of the health statistics and working with states to improve their Vital Statistics systems. He has 32 years of experience in health statistics and IT at the State, National and Non-Profit levels in the area of vital statistics. And joining Mr. Atkinson is Michelle Williamson, a Senior Health Informatics Scientist at the CDC in the National Center for Health Statistics. She has been a Registered Nurse for 35 years with 12 years' experience in Informatics and represents NCHS in Standards Development activity in the Public Health and Emergency Response workgroup, in the Standards Development Organization, HL7 and is also engaged in the Quality of Research and Public Health Committees at Integrating the Healthcare Enterprise, IHE. So, with that panel, and description of who those panelists are, I would like to proceed with the first presentation by Ms. Coyle. Let's see, have we got that lined up here? Bring up that presentation please. Thank you. So, Ms. Coyle, would you please proceed with your presentation.

Emily Emerson - American Immunization Registry Association

Hi, this is Emily Emerson, and actually I'll be presenting.

Arthur Davidson – Denver Public Health Department – Director

Oh, okay, thank you.

Emily Emerson - American Immunization Registry Association

I believe Rebecca is on the line, too.

Rebecca Coyle – Executive Director, American Immunization Registry Association

Thanks Emily.

Emily Emerson - American Immunization Registry Association

Okay. Thank you and good morning to everyone. Again, we'll just kind of jump into how the American Immunization Registry Association has been working on these issues regarding bidirectional exchange between EHRs and IIS, so I will give you a brief introduction to AIRA, we'll go over the barriers to bidirectional exchange, what we feel infrastructure would be needed to help further that exchange, some recommended strategies as well as health impact and cost savings.

So the history of AIRA is, we are a membership based, non-profit organization that began in 1999. AIRA currently has over 230 members, representing about 63 states or regional public health agencies, 7 businesses such as vendors and private consultants, 7 individuals, 5 affiliates which are other non-profit agencies and one sponsor. Our vision is to have a healthy, fully immunized community supported by the electronic sharing of information and our mission is to promote the electronic use, tracking and sharing of complete immunization records for people of all ages. Thus our purpose is to help support and promote the development, implementation and interoperability of immunization information systems through partnerships, peer and professional education training and resource development.

And we have several key partnerships. We are funded primarily through a cooperative agreement from the CDC, through their National Centers for Immunizations and Respiratory Diseases, the IIS support branch, and as you can see here, some other key partners that we work with; the Association of Immunization Managers, Every Child by Two, Public Health Informatics Institute, Indian Health Services, American Academy of Pediatrics, the Public Health Data Standards Consortium, HL7, American Health Insurance Plans and the Joint Public Health Informatics Task Force. And we did have a role with both Stage 1 and Stage 2. We compiled responses during the public comment period and in both instances, we really provided a forum through which other state IIS programs and interested organizations and individuals could really combine our efforts, so we had a lot of meetings and discussions, sharing knowledge and we did provide feedback to CMS and ONC, and so we did submit comments during the public comment period on Stage 1 and Stage 2 proposed rules, on behalf of the IIS community.

And we do have several initiatives currently that are really related to the work of what we feel Stage 3 will be, which is the more bidirectional exchange. First is our Standards and Interoperability Steering Committee, I'm a co-chair of that, along with Rob Savage at AIRA, and we do have even a subset, a new little workgroup called the Web Services and Real-Time Data Exchange Work Group that is doing some specific work as well. We've been involved for years now with bidirectional exchange standards. So for instance, we have had HL7 messaging for many years now, that would support bidirectional exchange, and more recently we've worked on transport standards, which our recommendation is to use a SOAP web service using a WSDL, and I'll go into that in just a little bit more detail. We do, every year, have a very concerted effort of a best practices workgroup that gets in place and this year we'll be tackling data quality, and we are also working with some of the workgroups at HL7 on creation of an immunization history CDA; so, we're also looking forward to how can we get immunization content… or make sure it's complete in the CDA documents.

Now some of the barriers that we've encountered, and one really more recently is, the kind of a lack of a good definition of some of these terms. So when we say bidirectional, what are we really meaning here? Are we talking about just the submission of an immunization with an acknowledgement return, or are we talking about a query or a specific immunization record from… let's say from an EHR to a IIS, and returning that record. So, there's just kind of all these different definitions that are further spelled out on the slide, that we're in our smaller workgroup are trying to make sure we all understand what we mean

when we say bidirectional. And so at this point in time, bidirectional to us means… could mean any of those four descriptions there so including query by demographic information and return of multiple or possible matches.

So, if you query a system for one person, you might get back 5 or 6 that then a user has to kind of figure out which is the one that they really want, and including as well requesting and returning all the vaccine forecasting, which is so core to what IIS' do. And then the concept of real-time; what does that mean. There's synchronous, which is an immediate response, asynchronous, which is you submit a job or a request and you get a response later in the day or the next day. And when we talk about response time, what do people consider real-time, is it less than 10 seconds, less than 3. In today's internet based world, it's really hard to ask people to wait even 10 seconds for a response to something. And some of the other barriers have been, just some EHR readiness for two-way communication.

For Stage 1 and Stage 2, we have HL7 messages for submitting updates on immunizations, but the HL7 query messages have been well-formed for many years and unfortunately, some are not in position… some EHRs are not in a position to be able to implement those. Even if they could implement them, can they read an HL7 message and incorporate them and display the results, you know, back to their user. That's something too that not everyone is able to do yet. And then kind of the whole person/patient management, can the EHR do duplications on their side, with results they get from the IIS, including immunizations. I mean, most IIS' will return all immunizations on a patient with every query, so, then it's up to the receiving system, in this case let's say the EHR, to have to figure out, okay, do I already having this shot in my record. And that is a huge burden that has to be faced. And then those that can display the data from an IIS, may not be able to actually embed it well into the EHR, so sometimes it's a read only or a view only screen, or it's not even part of the immunization grid; so, it's not really a part of the true immunization content within the EHR.

There are some confusing messages nationally, surrounding required transport; Stage 1 was silent on transport standards and now there is SOAP web services being discussed versus the direct, secure email versus any legacy solutions that are already in place, and you know, really through our work with the CDC and with other IIS stakeholders, we have felt that a SOAP web service meets bidirectional needs the best. There has been a lack of just "one size fits all" solutions; not one solution does work for everyone, because in each instance, the maturity of the EHRs in the state and the maturity of the IIS has to be taken into account, so it's been difficult, I know, at the national level to just one method to point to or one solution to point to. There is some concern about the uncertainty of sustainability of the funding for HIEs, so, not every state has an HIE that is ready to go, that is working with IIS, so that is definitely caused IIS managers to not really know who to work with.

James Daniel – Public Health Coordinator – Office of the National Coordinator

It's the 2 minute warning.

Emily Emerson - American Immunization Registry Association

Pardon?

James Daniel – Public Health Coordinator – Office of the National Coordinator

I just wanted to let you know you've got a 2 minute warning, we are…

Emily Emerson - American Immunization Registry Association

Well, I'll try to go fast then. You can see the listed limited funding for Public Health where some IIS' have received funding, but it doesn't really meet the broader need and there is limited expertise nationally on kind of all of these issues. Some of the infrastructure we feel is needed, on the policy side, let's recommend SOAP web services with the work that the CDC's transport layer expert panel workgroup did, so it's using SOAP web services with the WSDL. So that SOAP WSDL is available, it's potable and it's operating system agnostic. It is approved and used by major EHR vendors. There are tools and training… regarding tools and training, the CDC does have experts who can assist with SOAP and AIRA can help provide support with that. And communication overall, let's create IIS specific messages in collaboration with AIRA.

So again, kind of reiterating, let's… what we would recommend is let's ensure that the Stage 2 rules require EHR certification for SOAP and WSDL as the recommended transport, just include AIRA as often as you can on status and progress and reviews of EHR and IIS bidirectional exchange. And definitely include AIRA on the creation of the NIST test cases for EHR certification as that will ensure that the immunization use case has exactly what IIS' and EHRs need. We have a huge emphasis on data quality, we need it to be complete, timely and accurate and it's so important for the areas listed there, including bi-directionality, you need complete data, the robustness of forecasting depends on data quality and vaccine barcoding functionality between… on the EHR side or the IIS side can help ensure that that data is complete. Next slide.

There are several health impact or cost savings; we can improve the health of the population because IIS' help prevent disease with reminder/recall; we assist with disease outbreak intervention. EHR IIS exchange can help enhance the patient experience of care because it will prevent that patient from getting any extra or additional immunizations that they don't need, because we're providing quality, acceptable and reliable services at the point of care. IIS' can help provide official complete immunization records and thus promote timely school entrance and attendance. And finally, the last slide, getting EHRs to IIS to have bidirectional exchange will definitely reduce or control the per capita cost of care, because again, we're preventing those costly over or extra-immunizations. It's eliminating duplicate data entry, so we have a seamless flow of data from clinical care to public health and it would really help reduce development efforts to maintain the clinical decision support at the EHR level, you know, rely on the IIS for that decision support and that will reduce cost on the EHR and the clinic side. And I think that was the last slide, so hopefully, I'm right under my minute.

James Daniel – Public Health Coordinator – Office of the National Coordinator

Okay, thank you so much. We'll move right on to Warren Williams.

Warren Williams - Disease Control and Prevention in the Immunization Information Systems Support Branch of Centers for Disease Control

Hello, can you hear me?

James Daniel – Public Health Coordinator – Office of the National Coordinator

Yes.

Arthur Davidson – Denver Public Health Department – Director

Yes, thank you.

Warren Williams - Disease Control and Prevention in the Immunization Information Systems Support Branch of Centers for Disease Control

Okay. Good morning everybody. My name is Warren Williams and I'll be speaking on some of the very similar themes that Emily just reviewed in her presentation. I don't think it's too much of a surprise, but there are a lot of similarities between what Emily just presented and what I'm going to talk about today. Some of our ongoing efforts, as Emily also mentioned, the IIS community has been very involved with a variety of projects to inform strategic and well thought out direction for immunization related Meaningful Use Stage 3. These include a very important effort to make transport layer recommendations. Obviously this is a very important aspect for bi-directionality to occur. We've brought together experts from the immunization community, EHR community to make sound guidance for a suitable transport solution that supports a meaningful bidirectional exchange use case.

We feel that web service models are the way to go and for the situation that we have to deal with, the SOAP protocol supports the current needs and is better suited for future ones. The recommendations technical support implementations like WSDL implementations are available on our web page. We've also done some work to clarify logic for IIS' and EHRs to support meaningful ACIP immunization evaluation and forecast decisions. Should a decision be made to send a forecast or an evaluation back to a provider group, these forecasting engines have to be well thought out and designed to support a clear, logical breakdown. We are designing these technologies or logic to work in technology neutral

ways that we hope can support a variety of different implementation scenarios. Finally, we provide a lot of staffing support for technical resources on HL7 guides, data quality guides, grantee support and education; these are resources when used strategically can mobilize a community and build upon existing infrastructure and capacity that already exists, to ensure a useful, meaningful, Meaningful Use Stage 3 project.

Additionally, as Emily mentioned, we've initiated a 2-D barcode. This is an important pilot project that is just beginning to unfold, but we feel may have tremendous applicability in the use of integration standards, improvement to patient safety, affixing data quality and use of technology. The barcode project is exploring the use of a 2-dimensional barcode on vaccine vials and syringes. It's being pilot tested in 10 states with 3 vaccines from two different vaccine manufacturers, involves the use of scanners technology, barcode and standards organization and of course, EMR interface standards. These new ways of identifying vaccine product lot number and expiration date should do great things for improving accuracy and perhaps, provider efficiencies. However, system impact changes will have to evolve over time and a Meaningful Use Initiative may help to catalyze the needed investment by EMR vendors.

Next slide please. Some of the barriers, these are also similar to what Emily presented and there are many. The maturity and capacity of both the IIS and EHRs needs to be considered. Obviously, as time goes on, these will improve. We hear a variety of mixed reports about EHR capacity to receive two-way data. Consistency is also a problem on both sides between EHRs and IIS; some versions of software have different functionality, states have different reporting requirements and some interpretations are different, although we try to minimize that as much as possible. And, as Emily mentioned, one solution does not always work, so we have to be flexible about our approaches. Health information exchanges roles and responsibilities, Emily also touched on this. These models have good promise for immunization needs, but the relationships, roles, responsibilities and resources have not been worked out on a large scale basis.

Finally there is a need, as Emily also said, to be exceedingly clear and use of consistent terminology about what the intention is going to be with bidirectional exchanges. Do we mean reports and acknowledgements in return, looking up a query, getting a history of conducting a query, getting an individual name, history and evaluation and forecast report. These need to be practical, provide long term notice and be exceedingly clear. Environmental barriers, this is probably not a surprise to anybody, but, we need to consider the staff turnover in systems and in operations, training and education in these areas is a concern, hiring controls and the burden of support and software development is also a concern.

Next slide. For needed infrastructure; flexible solutions are needed on transport and plan for the end state, not the starter state of what we want to see with a bidirectional exchange. Obviously we feel web service models over email approaches are the way to go. Proposing early in the stage where bidirectional exchange is going to be, keep it straightforward and simple. We also need to focus on data quality. We need approved and agreed upon protocols and procedures are needed. For example, we can't forget to deal with some of these very important data quality challenges, what happens when the lot number is not supplied or its wrong, what happens when the vaccine type doesn't match the route and site. Clarifying eligibility status issues are also a concern and these need to be addressed as we move into Meaningful Use Stage 3 bi-directionality impact.

My last slide on potential impact. I think these are… the immunization use cases are great examples between the intersection of clinical medicine and public health. Both sides EHRs and IIS' have a tremendous opportunity to benefit from each other's contribution and both can serve important needs for both the clinician and the public health professional. Bi-directionality is where we need to be headed and some examples are already happening in the IIS community and ultimately this is very similar to what Emily said, that the enhanced operability between IIS' and EHRs will result in better data quality, better clinical decisions, sufficient delivery of vaccine resulting in less extra-immunizations which has cost savings implications. We look forward to slogging ahead with Stage 3 Meaningful Use efforts. I think that's all I have. Thanks.

James Daniel – Public Health Coordinator – Office of the National Coordinator

Thanks so much. We're back on schedule and we'll move on with our presentation on VAERS.

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

Hi. This is Tom Shimabukuro with the Immunization Safety Office at CDC. Thanks for having me and today I'll discuss CDCs work with the Vaccine Adverse Event Reporting System and linkages with electronic health records. Next slide. So VAERS is a national spontaneous reporting system for adverse events following vaccination. We conduct post-marketing surveillance in VAERS and various success reports from healthcare providers, manufacturers and the public. Signs and symptoms of the adverse event are coded and entered into the VAERS database. VAERS is jointly administered by CDC and FDA and is authorized by the National Childhood Vaccine Injury Act of 1986. Next slide.

The primary functions of VAERS are signal detection and hypothesis generation, specifically detecting new, unusual or rare vaccine adverse events, identifying potential risk factors in vaccine recipients for particular types of adverse events, monitoring trends in known adverse events, particularly increases and identifying vaccine lots with increased numbers or types of reported adverse events; also, to rapidly identify and respond to vaccine safety concerns and to respond to urgent vaccine safety issues and public health emergencies; for example, vaccine safety monitoring during the H1N1 program. Next slide. This slide is in here primarily for reference. I just want to focus on two limitations; the first is stimulated reporting and I will get into that in the next slide, and I want to reinforce that generally VAERS cannot assess if a vaccine caused an adverse event, we have other systems in place to assess causality.

Next slide. This is a VAERS report and I believe you're provided with a PDF copy of the VAERS report. Generally, there are three areas, demographics of the reporter and of the recipient of the vaccine, description of the adverse event and then description of the vaccine or vaccines that were administered. Next slide. So this is a graph of recent VAERS data as far as number of reports and percent of reports that are administered through our online system, and the online reporting, the percent of reports submitted online is in the percentage above the bars, and that is different than the electronic health record linkage that I'm discussing, but that's just to give you an idea; we do have an online interface to submit reports. And just to get back to the issue of potential stimulated reporting, you can see from 2007 to 2010, it looks like a pretty… fairly significant jump in the number of reports. There were two significant events that occurred. In mid-2006, human papilloma virus vaccine was licensed and recommended, as a new recommendation by CDC's advisory group. And also in 2009 and 2010, we had the H1N1 vaccination program and it's things like this which can result in stimulated reporting and I just wanted to show you this graph just to give you an example of the data and things you need to think about when you look at VAERS data.

Next slide. This is just a breakdown for year 2011 of the types of reporters who were reporting into VAERS; 38% from providers, healthcare providers; 27% from manufacturers, 11% from parents and 24% other and that other can also include providers that may have not specifically checked the provider box on the VAERS form. This is all vaccines averaged; there is quite a bit of variability in individual vaccines as to who actually reports, but this is an average. Next slide please. Moving on to our projects with linkage of EHRs to VAERS reporting; I will describe our 2005 pilot project. This was conducted at a managed care organization. The MCO used an EHR algorithm that generated prompts for providers to identify possible vaccine associated adverse events, so, these were computer generated prompts in the electronic health record, that prompted the provider to think about whether they should proceed with reporting an adverse event, and they could proceed, based on their clinical judgment. The managed care organizations generated a specific HDML version of the VAERS form which was partially prepopulated with patient information and the provider filled in the non-prepopulated fields to complete the form. The completed electronic file was sent back to the provider and the provider printed and faxed the form to VAERS; so, although there was automation with EHRs on the front end, the actual submission process was a manual submission process to VAERS, similar to how normal reports are submitted. The study site observed a proportional increase in submitted VAERS reports, but there was a limited quality and completeness assessment of the actual reports.

Next slide. So we have a follow on project, which is building on the 2005 pilot. It is a similar process to trigger a prompt to report to EHRs with some enhancements. There's flexibility to customize the trigger using a combination of variables such as diagnosis, lab tests, allergies, prescriptions; so, it's a bit more of

a smart algorithm. There is a shift to an updated platform that will be compatible with all modern EHR systems in the 2005 pilot that was specific to MCOs EHR system. There is more information available to the provider that will appear in the prepopulated form and most importantly, there is a built-in capability to directly or electronically submit to VAERS via secure message. The reports will be vetted by the clinician prior to submission and free text comments are allowed, so, there is clinician input into these reports.

Next slide. As far as our planned evaluation for this project, we plan to assess the proportional increase in VAERS report submissions. This is really a national baseline versus study site comparison; also characterize the types of health reports reported and whether the prompted reporting resulted in a change in the proportion of serious reports, and evaluate the quality and completeness of electronic VAERS reports submitted from the study sites, compared to traditional provider reports from all other venues. So, that's really a comparison of the EHR submitted reports versus our traditional manual submissions.

Next slide please. So as far as the potential benefits of VAERS EHR interoperability, certainly there is the potential to facilitate reporting vaccine adverse events from providers. The EHR generates a prompt for providers to allow them to consider whether they should think about submitting a VAERS report. There is pre-population of many of the VAERS form fields from the EHR and also the capability for direct electronic submission to VAERS from the EHR platform. There is the potential for greater accuracy for some VAERS form fields, so, fields like date of birth, vaccination date, vaccine type, vaccine lot number; these are things that are captured in the medical record as a part of standard good medical practice and we anticipate that there could be the potential for increased accuracy for these fields. There will be less time and resources devoted to manual data entry; this is as the VAERS contractor and also for providers entering data into the form. So, the potential for cost savings and possibly redirecting resources at the VAERS contractor, this feeds into the next bullet which is less opportunity for transcription errors. So, manual reports that are submitted either through mail or faxed to the VAERS contractor, those need… there's a significant amount of data entry or taking what's on the paper form and putting that into the database. If we are getting these reports electronically, there'll be less chance of transcription errors and also in the previous line, less time and resources to actually doing this manual entry.

Next slide. Potential concerns we have about EHR direct reporting to VAERS. At the top of the list is certainly patient privacy. There is a substantial amount of sensitivity around electronic transmission of patient health information from EHR platforms to government databases; that's true for adverse events, I'm sure it's true for electronic health records in general. There is current incompatibility with EHR and VAERS form fields, so, if you get a chance to look at the VAERS form, there are specific fields in there which wouldn't necessarily have a specific field in the EHR where there could be a direct transmission of data into that VAERS form field and so that's something we would need to work on with the EHR system. Automatic pre-population may result in bypassing or shortcutting the clinical judgment step. We really value clinician judgment and we value the clinicians going through the thought process of submitting a VAERS report and there's potential loss of detail and quality in the clinical description for adverse events; this is box 7 of the VAERS report, if there is just an automated pre-population of that; and that's a concern for us. And also comparability of reports. As you saw from the previous pie chart, about 40% of recent VAERS reports are submitted by providers and EHR direct reports to VAERS may not be comparable to non-EHR reports from different reporter types, including traditional non-EHR provider reports.

Next slide. So just to summarize, VAERS is fundamentally different than many other types of public health surveillance systems. A high degree of clinical judgment is used in the reporting process for providers and we value high quality provider reports that are submitted to VAERS. It can be more complicated that automated capture of counts of basic diseases or treatment reporting. CDC and FDA recognize the value of automation and linking EHRs to VAERS reporting and that's why we have conducted these projects and we are currently conducting and going to do a thorough evaluation of the project we have ongoing. We are working to evaluate the feasibility and utility of establishing these linkages of EHRs to VAERS and discussions are underway, both internally and with our partners at FDA on standardizing the messages. There are trade-offs between quality… trade-offs between efficiency and quality and completeness potentially exist; I think I've described that. Like I said, we value clinical judgment, we value detail that's put into the description of the adverse event and we have to consider the trade-off between the efficiency of automated reporting and the completeness and the detail and the

value we get from a very thorough provider report. And so finding the appropriate balance is important. Thank you, and that's the end of my presentation.

James Daniel – Public Health Coordinator – Office of the National Coordinator

Thank you very much. We'll move right on to David Birnbaum talking about Healthcare Associated Infections.

Dr. David Birnbaum - Washington State Health Departments Healthcare Associated Infections Program

Good morning. On behalf of the Council of State and Territorial Epidemiologists, Healthcare Associated Infections Subcommittee, thank you for this opportunity to describe work that we've done to promote efficient and effective reporting of healthcare associated infections. Slide 2. As briefly summarized on my second slide, CDC's computerized reporting system for HAI data has been evolving since its origins in the 1965 pilot project, CHIP was replaced in 1970, when the National Nosocomial Infections Surveillance System or NNIS was launched, which then became the mainstay for hospitals that wanted to monitor their performance through national comparisons. By the time the modules of NNIS were incorporated into CDCs new and larger National Healthcare Safety Network in 2005, the voluntary group of participating hospitals had grown in membership to 320 in 42 states. The new NHSN system very rapidly grew in membership as it became a secure data network through which mandatory public reporting became established, first under state laws and more recently by federal agency mandates. Numbers still grow almost daily, but by the beginning of this month, over 8,000 facilities of various types were enrolled participants.

Slide #3 gives a more detailed picture of the types of facilities participating. Mandatory public reporting first affected acute care hospitals, so it is no surprise that this has been the largest category. Over 90% of the nation's hospitals already are enrolled participants. As mentioned earlier, CDC's computerized reporting system has continuously evolved over the past decades and it continues to do so. One of its latest developments involves automating the data input step. Manual data entry by infection control professionals, one case at a time, has been the norm for many years, but the volume of data already required, especially for surgical site infection reporting, is becoming overwhelming without automation. NHSN started support for more efficient batch uploading by accepting comma delimited ASCII flat files as an intermediary solution. NHSN simultaneously provided implementation guides to more than a dozen third party software developers for several years, so that hospital computer systems would be able to upload HAI data through HL7 CDA messaging.

Nationally, 482 hospitals already have advanced to this cutting edge CDA step and here in Washington State, where I manage the Healthcare Department's HAI program, 6 hospitals have been using HAI surveillance software products like TheraDoc, MedMined or SafetySurveillor to upload data to NHSN via the HL7 CDA option. The infection control professionals in those hospitals tell me that their experience has been very positive, the resulting process much more efficient, giving them time to focus on job #1, preventing infection and monitoring surveillance results, now that they're able to spend considerably less time on data entry.

So the fourth slide. One of the questions you asked me to address is what we're working on that can help inform Meaningful Use. This fourth slide, borrowed from a Federal Agency presentation, briefly explains the nature of NHSN. NHSN is a well-established, secure surveillance system that encompasses reporting of various types of device or procedure associated, healthcare associated infections in patients, compliance with various best practices for prevention by Allied Health Professionals, patterns of antibiotic use and emerging drug resistance and outcomes among healthcare workers after occupational exposure to blood borne diseases. State Health Department HAI Programs across the nation all rely on NHSN as our data source, as does CMS for HAI information that it posts on Hospital Compare and CDC prepares periodic national summary reports from this rich database. In today's world of e-Health initiatives, NHSN has been very forward thinking in its work to transform data entry from internet based screens to HL7 CDA messages that can be flowing seamlessly from electronic health record systems.

Slide #5. Another question that I was asked to address is barriers my community has faced. There have been many during this modern era of hospital infection control, but perhaps one consistent issue has

been sparse resources within the infection control program of hospitals and other types of healthcare facilities. One of the major hopes of infection control professionals about mandatory public reporting was that it would focus more attention on the need for adequate resources to accomplish the assigned work within the facilities. Unfortunately, that gain has not been the norm yet, and it's fair to say that the hospital epidemiology and infection control community is now feeling left out of planning for Meaningful Use 2. In informal show of hands polls that I have taken during a number of my presentations at regional and national meetings, fewer than 1% indicate they have been engaged in their own facilities Meaningful Use planning. CMS has imposed a growing burden of infection reporting requirement that increases workload now, and that work has been accomplished. But Meaningful Use has not commensurately recognized that work in its core requirement specifications. We hope this can be remedied in Stage 2.

Moving on to slide 6. This next slide is the list of the HAI events on which CMS requires reporting. Each involves multiple data elements so that rates can be computed, risks stratified or risk adjusted and validated. Acute care hospitals had to start reporting central line-associated blood strain infections, which many people call CLABSI, last year, to which catheter-associated urinary tract infections, commonly called CAUTI and surgical site infection, SSI, are added this year. Dialysis facilities will start reporting intravenous antimicrobial starts, positive blood cultures and signs of vascular access infection this year. Other requirements affect a range of facility types in 2013 and 2014. The workload burden is already here, which is why we need Meaningful Use to deal with this issue in Stage 2.

Moving on to slide 7. I was asked to comment on infrastructure and recommended strategies to achieve the desired results. In terms of policies, rules and laws, these already are in place and being enforced. Ample tools, training and communication resources are comprehensively documented and freely available on the NHSN website and at the State level, we provide support. State HAI programs, quality improvement organizations, patient safety organizations and now Partnership for Patient's Hospital Engagement Network contractors all access them as they guide healthcare facilities in surveillance and prevention activities. As to strategy, I suggest it is as simple as promoting acceptance of NHSN already being the gold standard model. It's used for HAI data reporting by the various American Federal Agencies, virtually all State HAI programs and several other countries have modeled their own national surveillance system after NHSN.

Slide 8. Let's move on to impact, cost and economic savings questions that you asked me to address. Recognition of HAI reporting via NHSN will not add any burden at the provider level. The work of infection surveillance, prevention and control was mandated decades ago by an accreditation requirement. The work of data uploading already is a significant and growing burden, for reasons explained earlier. We did a survey of SSI reporting readiness, Surgical Site Infection reporting readiness a couple of years ago in this state and found that up to 25% of an entire hospital infection control programs staffing resources could become consumed by manually uploading the required surgical site infection data alone. This kind of reporting, surgical site infection, requires more denominator data elements than other types of infections, because these are essential in order to produce meaningful rates that are risk stratified or risk adjusted and validated. Software already is available for infection surveillance, but whether standalone or part of a comprehensive electronic health record system, it is expensive. So, we have an opportunity and we have a need today, to ensure that hospitals and other facilities acquiring computer hardware and computer software to meet Meaningful Use requirements, will ensure that the needs of their infection surveillance programs are satisfied. In turn we can provide you with very successful business cases and use case stories. Our purpose, of course, is data for action and action is warranted because HAI is an important cause of preventable morbidity, mortality and healthcare cost.

Slide 9 please. HAI is relatively new territory. If you could push the space bar one more time; thank you. This nice slide shows where HAI would rank if juxtaposed onto leading causes of death in which public health has already long been involved. We've known for over a decade that depending upon which estimation estimates one accepts, HAI would rank somewhere between the nation's fourth and fourteenth leading causes of preventable death. Slide 10. So, having reached my last slide, a graphic provided by Austin & Chrysler at CDC, I'd just like to add that unlike many single purpose public health reporting systems, NHSN serves many purposes for many stakeholders. Individual healthcare facilities, statewide programs, public health departments, quality improvement and patient safety organizations, Federal

agencies, university-based researchers and now a widening public audience all rely on NHSN for their individual purposes. NHSN serves adverse event reporting and quality reporting to drive and guide improvement efforts. Clinical reporting that can help guide patient care decisions regionally and locally and case reporting that can alert health authorities to the emergence of new pathogens and antimicrobial resistance. I hope this brief presentation has given you a better understanding of the secure data network that serves the very core of my profession or communities information needs. Thank you for your time this morning.

James Daniel – Public Health Coordinator – Office of the National Coordinator

Thank you David. And we'll move right on to Delton Atkinson to talk about Vital Records.

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

Good morning. This presentation will be done by both Michelle Williamson and myself. Next slide. The Vital Statistics in this country is a state function with records under the sole authority of the states. We at the National Center for Health Statistics work in a collaborative mode with the states to improve the collection and the quality of birth, death and fetal death records. Now our eVitals Project is one of the initiatives that we have going here, and the goal of that project is to develop national standards to facilitate the national exchange of birth, death and fetal death records between electronic health records and the State Vital Statistics systems.

Next slide. And the key reason why this initiative was started was that a significant number of data items for vital registration are captured in the medical records for our birth, our death and our fetal deaths. Medical records have been identified as the preferred source to obtain the medical and health data that is needed to complete those certificates and third is that we believe that there can be improvement in the timeliness and the quality of the information collected if we are having this electronic exchange between the electronic health records and the state Vital Statistics systems. Next slide.

Michelle Williamson – Senior Health Informatics Scientist, Centers for Disease Control's National Center for Health Statistics, Classifications and Public Health Data Standards

On the next slide you'll see that we've tried to identify a few categories for classifying the information, some of that medical and health information that Delton mentioned that we need for the certificate of live birth, in particular. So as you see we have prenatal care information, risk factors, labor and delivery information, as well as specific items about the newborn. If you look at some of the details that are provided here, you see that most of this information, probably all of this information, is either captured in a paper medical record or an electronic health record system.

Next slide. On this slide, we're showing what NCHS has done in terms of our support for developing standards for eVitals. And in this particular slide, we're showing how we want to put a focus on capturing information at the point of care or the point of contact with the patient. So, we have a mother with her prenatal care visit, she's providing information that the birth information specialist can capture and enter in an electronic health record system. You can directly capture information during the birth event, during the documentation that's being provided by the nurse or the physician; and providing an opportunity to directly exchange that information with an electronic health record system to a vital record system. Here we're showing the particular vital record system being the birth registration system, and there are various others; ones for fetal death reporting and also for the death certificate system. We see sending this information, using a national standard, to the registrar, on to the State Department of Health and then potentially on to the National Centers or other Federal agencies.

Next slide. The next slide provides you with a high level overview of several of the standards initiatives that we've been engaged in. You can see that we started some of this work back in 2007 when we had a call for participation from various of our Vital Records stakeholders to participate in the standards work that we wanted to support. We formed a Vital Statistics Standards Committee and then that committee has provided support for the work that you see to the right of the timeline. One of the first activities was to develop a model using HL7's Vital Records domain analysis model as a format, utilizing UML as the basis for this, and this provided us with a way to identify modeling for the birth process, the fetal death process

and death and collecting the information that we need for reporting. We also created a vital records functional profile based on HL7's electronic health record system functional model, to identify what functional requirements would really be needed in an EHR system, to describe what we needed for vital records.

We moved from that work on to specification type work, in HL7 V2.5.1, and I will note that one of the reasons we started with 2.5.1 was to be consistent with Meaningful Use had identified for immunization ELR as 2.5.1. being one of the standards. Our group also, by the work of stakeholders, emphasized that V2.5.1 would be a good path for them to begin the process, rather than to move directly into CDA, which many of them felt they were not in a state to support. However, they did see the futility in working on that area and moving forward so that CDA would also be available. I'll also make one other point in this slide; we did some work with IHE to develop a content profile, very specific to the requirements for our specifications for getting that birth information and this will help guide pre-population from EHR systems to vital record systems.

Next slide. So to address some of the readiness issues, we've provided some of those areas that we think are key to making sure that you are ready for Meaningful Use. One is stakeholder engagement, and we have a couple of checkmarks there because we have been very engaged in collaborating with the National Association for Public Health Statistics and Information Systems, NAPHSIS, which is the National organization that represents the jurisdictions and states within the U.S. for vital registration. We also have worked individually with some of our state and jurisdictional representatives to provide support for our standards work. And then we continue to work with the standards development and standards-related organizations, HL7 and IHE. In particular, with IHE, we've also engaged with vendors by participating in the IHE Connectathons, both in 2011 and earlier this year, as well as in the HIMSS interoperability demonstrations, to show how we could really use vital records information coming from an EHR and pre-populate that information into a vital record system.

Next slide. We've also put a lot of emphasis on trying to make sure that standards are available. I mentioned already the modeling work, functional requirements and the messaging work. We are working very hard on the messaging standards right now and we should have V.2.5.1 standards for both death reporting and birth and fetal death reporting by the next few months. We have begun the work on CDA, we just balloted with HL7 a CDA death reporting implementation guide and by September we plan to ballot the next guide, the CDA birth and fetal death reporting. We also want to look at certification criteria; we know in the past that some of the certification bodies have referenced HL7's EHR functional model and the profiles that came out of that model for certification. We hope to explore the potential for maybe using the EHR as vital records functional profile, also for that purpose.

Next slide. Our next effort will also be focused on pilot implementations; now that we have standards developed, we want to see what we can do to pilot test some of these with some of the states, so we want to focus maybe one project on the CDA work, using the birth data, and then a V2.5.1 focus implementation on the death data. Next slide. Now when we look at some of the barriers to moving forward with eVitals standards, one of the barriers that came up during our collaboration with our Vital Records stakeholders was their focus on the fact that they are the ones who are legally responsible for the registration of vital events, and so they express some concerns about getting information directly from an EHR using pre-population to do this. So we've tried to address some of that in our dialogue with them, coming up with mechanisms to make sure that they can have a confidence in getting the information from EHR systems. We also realize, based on the feedback we've received also from our VR stakeholders, that funding is a concern. They are trying to see what they can do to implement these types of standards, they're concerned will there be funding to help them transition their systems and so forth. EHR vendor adoption is a key component that needs to happen. I mentioned that with IHE we've been working with vendors as well, but unless vendors incorporate these standards into their products, to make sure that the vital registration requirements are met, this will be a true barrier. And we need to make sure that vital record systems vendors also are able to receive the information on the other side.

Next slide. So, for the strategy for success, we think we've already started in that path. We are utilizing the existing infrastructure with CDC/NCHS's collaboration with NAPHSIS. We are working to educate out vital records stakeholders, begin the process of training through a participation in national meetings and

so forth. So, this is a huge effort towards making sure that we are successful. We also are looking at how we might be able to help provide funding support, so pending funding availability; we hope we can provide some support for these future projects. And then we feel it's essential to continue to participate in the national standards development activities, so that we can make sure that these standards are developed to represent truly what is needed for vital registration.

Next slide. As far as the impact of eVitals standards, we'll say just even looking at what we've done so far, the support that we're getting for the national standards development and standards-related activities with IHE and HL7 has been tremendous. We're also starting to engage those who have an international interest in this effort; we're working at IHE in collaboration with France in some of that effort. We're also engaging with the vendors. I mentioned the work at IHE, the testing at the Connectathon, so that is also having a huge impact on moving forward. And we're getting more and more interest and solicitation from people who want to know more about these efforts. We've been asked to provide a demonstration at the upcoming NAS' NCHS conference to show the demonstrations that we did at HIMSS. So, the interest is growing and we are actively planning for the future of pilot projects, to see this moving forward.

Finally, as far as impact on cost, quality and timeliness of the data, I would say that's all to be determined as we move forward with our pilots, but we strongly believe that moving forward with these efforts will help to reduce some of the redundant data that is going on right now in terms of collecting that information in separate standalone systems and we believe that this will improve the timeliness and the quality moving forward. And that's our last slide, the next slide is just our contact information and we appreciate the opportunity to provide this information.

James Daniel – Public Health Coordinator – Office of the National Coordinator

Thank you so much Michelle and I'll turn it back over to Art, so we can start our question period.

Arthur Davidson – Denver Public Health Department – Director

Thank you, all of you presenters for your thoughtful comments and preparation. I'd like to open up the question period and see if, I think a few of the members of the committee have joined since the original roll call, is there anybody who has a question at this moment?

George Hripcsak – Columbia University

Art, this is George. First one comment, I thank you for the clarification that we need to clarify what we mean by bidirectional. I can say in general we were, at least my understanding was we were thinking at the high end, at not just the simple acknowledgement, but even at the high end, as you point out, there are different functions, so, that's very good. Thank you for that. Number 2, I'd like to make the point that I don't see this as a choice between manual reporting and EHR-based reporting because they're two very different things. It's like the difference between when you fill in a research database on purpose versus where you gather data from the EHR, they may complement each other, for example. So, I try not to tell people I can replace one with the other. You might, down the road, say I don't need one of them, but you might need one, the other or both, because the data you get from the EHR is, just no matter how you approach it, it hasn't undergone the manual curation that really makes it different than EHR data. I was wondering if you have any comments on that.

Arthur Davidson – Denver Public Health Department – Director

George, was that directed to anyone individually or…

George Hripcsak – Columbia University

Actually, it's to several presentations, so not one, it actually went for several.

Arthur Davidson – Denver Public Health Department – Director

Any of our presenters like to speak to that? I mean, I'll go ahead and jump in because I had that same question with regards to the last presentation, what percent of the birth record would be completed… I know you gave some examples of what would be completed, but what percent of the birth record for vital stats would be completed by the EHR versus… there may be 100 or 200 variables, what percent would not be completed?

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

On the birth record, about half of the information that is needed to complete the birth record is coming from the electronic medical records. The other half is coming directly from the mother, in terms of some of the legal requirements like, what are you going to officially name the child and some of the other things that have to come directly from the mother. But, when we look at the data items that are needed to be collected, it is about half is coming from the medical records. Now the process that happens right now is that a birth clerk in the hospital would go to the medical records and manually extract that information from the records, be it in an electronic way or in a paper-based way, and so that… and then she would enter that information on a paper form and then enter that information manually into the State's web-based electronic birth registration system.

Arthur Davidson – Denver Public Health Department – Director

Thank you. And, Tom, I know that you described a system that in the MCO study that involved also some manual work, as George was asking about. Would you have any comments here?

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

I think we would agree with the initial statements about the electronic processes complimenting the manual process, not necessarily whole scale replacing it. I think the concern that we have is we want to make sure that as we move forward, increasing these linkages to EHRs and increasing automation procedures, we want to make sure that we don't lose or bypass or shortcut that process that a clinician should go through when they think about submitting an adverse event and really, the concise detailed description of the adverse event, which is in box 7 of the VAERS form, which is really the most valuable information in… one of the most valuable pieces of information in the VAERS form, we want to make sure that as we move forward, that we don't lose that kind of detail, because we are moving towards more of an automated process where some of these fields are pre-populated. I think that is our concern; but, we agree that it's important to move forward with this and I think we agree with that initial statement.

Arthur Davidson – Denver Public Health Department – Director

I'm just going around in a circle here, so David, in your description of the HAI reports to the NHSN, what… for those sites that are more advanced, as you described maybe 6 hospitals in Washington, do those sites still need to do manual efforts, or can that be totally automated?

Dr. David Birnbaum - Washington State Health Departments Healthcare Associated Infections Program

That's an interesting question, thank you for asking. There are incredible, light-year ahead sort of places, like the LDS HELP System in Utah, where they've been able to demonstrate that heuristics within the computer system can identify anything a human being can identify, looking through the individual medical and laboratory and clinical and pharmacy and radiology records. So, they've reached the point where they can identify the issues, identify the cases and they've even moved ahead of where the average infection control program is, to be able to apply research designs to identify patients who are beginning to go sour, and say this one requires closer attention now, before there's a problem. I don't know of anywhere else that's done something that advanced.

The majority of the hospitals, including the ones that are leading edge here, you have to separate out the case review from the case reporting step. The case review, in most hospitals, really does rely on a trained professional who can apply the definitions, understands all of the clinical nuances and make the decision as to whether the criteria are satisfied to call something an infection. There have been a number of studies looking at alternative sources of information, for example, billing data, the ICD-9 codes, and they've found them to be notoriously unreliable in estimating the true rates of infection, compared to having somebody with a clinical background going through and reading those records. So, unless we get to the like Star Wars future, where the LDS system is everywhere, we are going to be looking at people who still want to spend their time out there on the wards, interacting with the staff, looking for opportunities to comment on improvement, while they review the clinical records. But the more we can then automate the reporting, like once they've said yes, this one fits the criteria, just push the button;

rather than yes, this one fits the criteria, now I'm going to spend 5 minutes entering the data. That's where the true benefit will come.

M
Yeah.

Arthur Davidson – Denver Public Health Department – Director
Thank you. George, did you have any follow up there?

George Hripcsak – Columbia University
No that's good, thank you.

Arthur Davidson – Denver Public Health Department – Director
Okay. Any other members of the workgroup or the subgroup with a question?

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs
Yeah. This is Charlene.

Arthur Davidson – Denver Public Health Department – Director
Hi Charlene, please proceed.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs
I've got actually three comments. Number one, I really just as a comment like an end-to-end process; so when I look at immunizations and the adverse event reporting and all, it starts pulling together something that was started in Stage 1, so, that's just something that I find really powerful. General comment. But, what I really want to know from each of the presenters, in each case, there's really two aspects I'm looking at. One, the data has to be collected and it worries me, and I know you're all working on the standards process which I think is great, and you're all doing the right stuff; but, is there alignment amidst the data elements that are captured, such that we can capture them once and use them for multiple uses, and does that kind of work happen among these different agencies and reporting systems. Because, from an EHR vendor perspective, we can capture this data once and we can report it, I mean, you have to add some additional functionality, but, it gets you going in this. So, if you could comment on that in terms of, has there been an analysis looking across these different reporting requirements and the data to see where there's a sweet spot, if you will?

Michelle Williamson – Senior Health Informatics Scientist, Centers for Disease Control's National Center for Health Statistics, Classifications and Public Health Data Standards
Hi, this is Michelle Williamson from NCHS, I'll take a first stab at that. I'll say two things come to mind. First is, we have been engaged in submitting our user story related to vital records, to the ONC Public Health Reporting Initiative. So, we are working with that group to do some data modeling, comparison of our data elements across the child health user story in particular, and we're hoping that that might help with some of the harmonization activities. The other is, in the work that we've done at IHE, we did an analysis of just looking at some of the, like SNOMED codes that an EHR system would need to capture and we are working, or planning to participate in an activity that's coming up with the American College of Obstetrics and Gynecology and some other OB type groups, that are looking at how we might harmonize the information that is captured, so that it is consistent with what we're trying to get for Vital Records as well. So, I know that there are some activities moving forward in that direction.

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics
And let me say something else, within the Vital Statistics community, we at the National Center produce U. S. Standard Certificates for live births, deaths and fetal deaths and so states are, in terms of collection of that information, they are required to meet those particular data elements and specifications. We produce for them, national edit specifications which we are requiring that they include within their respective systems. And this is a part of their Vital Statistics contract that they have with us. Now, they

can add their own state-specific variables, but, from a national perspective, they must minimally be collecting those things that are in the standard certificates.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Yeah. Go ahead.

Arthur Davidson – Denver Public Health Department – Director

Go ahead Charlene.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

It was just again, I guess that we're trying to eliminate here, they can do that, but if the way the collect them isn't harmonized with how it comes in at the front end, be it a registration and/or an EHR system, and it's a separate system that's in place. I think we heard that in terms of the infection reporting, TheraDocs is there doing the reporting. So, again, I don't think we can necessarily break the processes, but we do want to get some of that information captured at the front end, because then you can ultimately add the intelligence to help us better manage those processes around infection or managing vital statistics capture or that type of thing. So, that was kind of where I was going.

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

And we completely agree with that, in terms of where we want to try to move this whole process and this whole system. Yeah.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Okay.

Arthur Davidson – Denver Public Health Department – Director

May I ask… Delton, in this description of the edit checks, are those mostly happening at the state level or are hospitals incorporating that in their EHR systems? Is that an engine only at the state?

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

Well, the states do the editing of the records, we here at the National Center, and there's about 6.5 million records, and we have a staff that does nothing and computer software that does nothing but review the edits and every record that fails an edit, every data item, we query back to the states and in some cases, the states that have to query back to the hospital for someone to look at the medical record. So yes, every record is evaluated and every record has to ultimately pass the review that we do here nationally.

Michelle Williamson – Senior Health Informatics Scientist, Centers for Disease Control's National Center for Health Statistics, Classifications and Public Health Data Standards

And one of the things that we've tried to do in identifying the functional requirements in our vital records functional profile is to include requirements that embed some of those types of edits that we have in the edit specification, within an EHR system, so we do hope that we will be able to limit the number of edits that have to occur at our end, if we can get those incorporated in systems on the front end.

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

And to limit a number of inquiries that have to go back to the hospitals because there was an error found in a particular record.

Arthur Davidson – Denver Public Health Department – Director

Thank you. Charlene, did you have a follow up or…

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Yes. The other thing, again, a couple of the speakers commented on the readiness… I kind of look at this in 2 dimensions; readiness of EHRs to support the various reporting efforts wherein some cases you've got both immunization registries was the example as well as the EHR is ready; there's just kind of like, we have either in the HIMSS analytics database or… is there data around that readiness profile in terms of either… I mean, I think this would be tremendously valuable. All of the initiatives are so powerful and so important that you're talking about, but starting to get a handle in terms of where we are across EHR vendors as well, certainly around the public health perspective in terms of readiness, competency, to actually move forward on these initiatives I think it would be really powerful to start to inform how we make some decisions among these different directions. Do you know if anyone collects that, because each of you commented on it, but I don't know if they've ever seen any real data around it.

James Daniel – Public Health Coordinator – Office of the National Coordinator

This is Jim. I know that EHRA is doing a survey of its members around some of the public health measures that they're just now finalizing the questions and will be putting that forward soon.

Arthur Davidson – Denver Public Health Department – Director

So Jim, is that around the current… the proposed Stage 2 or some of these that we're having discussion around in these listening sessions?

James Daniel – Public Health Coordinator – Office of the National Coordinator

A lot of that one is actually focused around immunization and bi-directionality, but, I think there could be essentially be an opportunity to expand that, since it has not been finalized.

Delton Atkinson - Deputy Director, Division of Vital Statistics, Centers for Disease Control's National Center for Health Statistics

And let me say in the Vitals world, because we're at the stage now where we are probably going to release a couple of task orders, one to a state on the birth side and then one to a state on the death side, where we begin to evaluate their readiness for this and then hopefully, to be able to pilot some of the standards. We do have one state, the State of Utah, that is right now, and they've got some other funding through CDC and are doing some very interesting things with that linkage of electronic medical records with death certificate, the cause of death information and in their particular state, when a physician is completing the record and if the person has died, then the information that is needed for the death certificate from the physician, is automatically brought up for him. They don't have to get out of the electronic medical record system to go into the vital records system, it's automatically brought to them and they complete it, but they don't have an ability to go back and forth and then that information is automatically sent to the state's Vital Records Office. So, we're in the early stages now of beginning to do some experimentation, some piloting in some different states, in terms of this whole area.

Dr. David Birnbaum - Washington State Health Departments Healthcare Associated Infections Program

This is David, if I could address some of Charlene's points from the HAI perspective. I think there are three things that are unique about what we're doing that directly impact your important questions. The first is stakeholder engagement. We have a very broadly representative advisory committee within this state, as do most states; so we really want understand the providers, the payers, the policy makers, the patient advocates, everyone who has a role in this to play. We also, in partnership with Universities, are doing outreach activity to engage segments of the broad public. We, in additional work with our graduate students, have identified there are at least 10-12 different segments of this public audience, each with their own information needs; so, we're trying to understand that better and tailor the end product to deliver and meet their needs.

We also understand that we really need to produce trustworthy information. So Washington, I think has been a leader… Washington State, in terms of our approach to validating the process that provides the data into these reports. We have designed our program, our validation program, around the International Organization for Standardizations ISO standard 2859 for sampling by attribute, and we have every hospital in the state participating in that ongoing annual validation, so that we can guarantee the level of

the quality of the data going into these reports. The other thing that's unique about what Washington State has been doing, and again this speaks to the idea of taking the data in and then using it for multiple purposes, my real interest in this is as a University Faculty member for research purposes.

So, I formed a collaborative with peers across North America. We've got a dozen faculty from many different academic disciplines, working on evaluation of the value of these kinds of programs and specifically, the return on investment from public reporting of HAI rates. We already put on one symposium, the proceedings have just been published. So, we are contributing through the literature to try and gain a better understanding of where the strengths, weaknesses, potential values, return on investment, may lie; because there are so many knowledge gaps facing all these programs, and we need to fill those as well as provide service.

Arthur Davidson – Denver Public Health Department – Director

Thank you David. Charlene, any other questions?

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Yeah, one more. And David, I think you spoke a little bit under your program, others may have relative… maybe it was Tom; this relative to FDA oversight. Now, from the vendor community and EHRs, there's a lot of discussion nationally now about importing when there's potential harm that potentially is caused, where an EHR is part of that. But in terms of… if there's... you know, we're all trying to prevent harm across our field and with multiple reporting means to do that, it seems like instantiated some of those reporting means. So, is your vision there's going to be multiple reporting means to manage and look at harm, for instance, relative to a birth event. I know I'm jumping a little bit far ahead, or is there something that starts to bring that together as we start to look at, kind of adverse event reporting, that type of thing? I know it's not necessarily targeted to the vaccine, but, it's in that domain space. Any comments on that, in terms of FDA oversight of this process relative to reporting, relative to patient safety?

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

This is Tom and I don't believe, I didn't hear anyone from FDA on the call, as far as FDA oversight, I would have to defer to FDA, as far as regulatory requirements for reporting adverse events. However, I will say that, theirs is jointly administered by CDC and FDA; CDC manages the contract and it was authorized by the National Childhood Vaccine Injury Act, and there are certain reporting requirements that go along with the Act for certain serious adverse events or events that are on the table, what's called the table of reportable events are required by providers to do report. But, like I said, as far as specific FDA oversight, I can't really comment on that, unless there's…

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

That's fine.

Dr. David Birnbaum - Washington State Health Departments Healthcare Associated Infections Program

This is David, I could jump in as well. That's a really good question that I wish you could ask me two weeks from now, because one week from now, there is going to be a data summit meeting convened by HHS to address the problem of all the different Federal Agencies all having different data sources, different paradigms, different standards producing results in their reports that don't always coincide with the same message; in some cases, contradict each other. So hopefully this data summit meeting will be one of the first places to start resolving which of these data are better for certain purposes and not others, and how can they be reconciled so that we use them intelligently and start breaking down the silos.

There is a very interesting map of all of the agencies and NGOs that impact on hospital reporting, which I had to draw up for strategic purposes, and if you'd like to have a look at that, I mention the University's Counsel and we just published our symposium. There is a Journal called Clinical Governance, and in an article entitled State and Federal Legislative Interests, in the second quarter issue, that's 2012, Volume 17, Issue number 2, Page 141; there actually is a figure that maps out all the different agencies and in our case, it's certainly not FDA, we have really relied on CDC, but there have been CMS and AHRQ

independent and there even have been elements inside of CDC that have been in opposition to each other. Ultimately I think it comes down to control by HHS and oversight by GAO.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Thanks. Yes, that would be in this space, that would be really helpful, but I do think that when we talk about cutting of like 30% of waste of the healthcare, we certainly seem to have some wonderful opportunities here to figure out how to work together on this. Thank you.

Arthur Davidson – Denver Public Health Department – Director

Thank you. I wonder Jim or Michelle, is ONC going to participate in that summit?

James Daniel – Public Health Coordinator – Office of the National Coordinator

I'm not sure, Michelle?

Michelle Nelson- Office of the National Coordinator

Yeah, I'm not sure either.

Arthur Davidson – Denver Public Health Department – Director

Okay, that might be something for us to follow up on at least.

Amy Zimmerman – Rhode Island Department of Health & Human Services

This is Amy and I've been on for most of the call. I did have one question.

Arthur Davidson – Denver Public Health Department – Director

Sure Amy.

Amy Zimmerman – Rhode Island Department of Health & Human Services

So, I came on a little bit late into the immunization presentation and my apologies for that, but, the question really is sort of around something that was mentioned under VAERS and then also a little bit on the AIRA presentation. I think it was mentioned with VAERS that things are sent to VAERS through secure email and I was wondering if that's a proprietary secure email, where does direct fit into that, and then I know that there has been controversy around sort of direct versus SOAP on the immunization side. My understanding is there are some states that are using direct, although that's not the recommendation. So, I'm wondering if there's any more that anyone can share around that as we think through this.

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

Hi, this is Tom. So I can speak for Immunization Safety and VAERS. So, right now there are three standard ways to report to VAERS. There's mailing in a printed report, there's faxing in a report or there's submitting a report through the online interface, which is an individual goes in and basically submits an online report. When I was talking about the linkages between VAERS and EHRs and the direct electronic submission, that's really a project we're doing with a single contractor, in this care it's a managed care organization that we've worked with before and we did a pilot in 2005 and this is a follow on project, and that's really in the R&D stage. It's something that we certainly are considering moving towards as we build our knowledge base and increase our capacity to do this. But that's really more in the kind of prototype phase right now, but what… the ways that reporters submit to VAERS right now is primarily a manual process, that's the standard way.

Amy Zimmerman – Rhode Island Department of Health & Human Services

But in that MCO project, were you then having from the EHR send through web secure email messaging to VAERS?

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

Yeah. So, the… in the EHR project, what happens is, just to briefly go through the steps again, the contractor has built an algorithm into the EHR to recognize when there may be a potential vaccine associated adverse event. The provider then, through the EHR, gets that prompt and makes a clinical decision if they want to move forward and submit that. If they do, then the EHR will pre-populate a VAERS form that they have created through their own EHR, pre-populate a VAERS form, the provider goes in and has an opportunity to free text complete fields which actually require a provider… which we want a provider to go in and enter some information, or if they want to edit some information. When the decision is made at that point for the provider to submit it, then it's a direct, secure submission, directly to the VAERS database through a secure message. So, that's an automated procedure and a direct, secure transmission; which is different than the way that we do it right now as a matter of routine practice.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right, and so when you say direct, you're talking about direct messaging.

Tom Shimabukuro, MD - Senior Medical Officer, Immunization Safety Office at the Centers for Disease Control

Yes, actually it's an HL7 message, it's using HL7. It's a direct message from the EHR, from the healthcare organization directly to VAERS. There's no… it really cuts out the manual process of receiving the paper form, and inputting the data manually into the database and then basically making an image of that form and posting it into the database. So, it is an electronic, secure messaging type system.

(Indiscernible)

Arthur Davidson – Denver Public Health Department – Director

I'm sorry I'm going to have to interrupt here, we have to open up the line for public comment. Would the operator please open the line? We just have a minute left or two for public comment.

Public Comment

MacKenzie Robertson – Office of the National Coordinator

Operator, please open the line for public comment.

Alan Merritt – Altarum Institute

If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-2976 and press *1, or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Arthur Davidson – Denver Public Health Department – Director

As we're waiting, I just want to thank the panelists today for their presentations. I know that there are probably many more questions that our subgroup will have and hope that we can call on you over the next weeks to months, as we deliberate to get further clarification about some of the things that might be of interest to our group or to the Meaningful Use Committee or the HIT Policy Committee.

Alan Merritt – Altarum Institute

We have no questions at this time.

Arthur Davidson – Denver Public Health Department – Director

Well, once again I want to thank you for the thoughtful comments, excellent presentations and discussion that followed. I appreciate everybody's time this morning and we look forward to hearing and learning more from you in the weeks and months to come. Thank you all.

W
Thank you.

M
Thank you.

James Daniel – Public Health Coordinator – Office of the National Coordinator
Thank you

MacKenzie Robertson – Office of the National Coordinator
Thanks everybody.

George Hripcsak – Columbia University
Thanks, take care.

M
Bye.